

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION

ST. FRANCIS MEDICAL CENTER,)
on behalf of itself and all others)
similarly situated,)
)
Plaintiffs,)
)
vs.) Case no. 1:07cv0031 TCM
)
C.R. BARD, INC.,)
)
Defendant.)

MEMORANDUM AND ORDER

This antitrust action is before the Court¹ on the motion for summary judgment filed by defendant C.R. Bard, Inc. ("Bard"), and on the motion for partial summary judgment filed by plaintiff and class representative, St. Francis Medical Center ("St. Francis"). [Docs. 266, 269] Also pending is a motion by Bard to strike the reports and exclude the testimony of Drs. Robert Litan and Hal Singer. [Doc. 264]

Background

Bard is a manufacturer of urological products, including urological catheters, and is the leading manufacturer of Foley catheters and related products. (B. S.F.² ¶ 1. B. Ex.-2,³

¹The case is before the undersigned United States Magistrate Judge by written consent of the parties. See 28 U.S.C. § 636(c).

²"S.F." refers to a party's Statement of Uncontroverted Material Facts and is cited only when the referenced fact is undisputed by the opposing party or when the dispute is not germane or genuine.

³"B. Ex.-2" refers to the exhibits submitted by Bard in support of its motion for summary judgment. "B. Ex.-1" refers to the exhibits attached to the declaration of Michael DiGiannantonio.

1.) "Urological catheters are used to drain urine from the body." (B. S.F.⁴ ¶ 1.) One of Bard's various divisions, the Bard Medical Division ("BMD"), markets and sells those catheters, including Foley catheters, infection control Foley catheters, and intermittent, or urethral, catheters. (Pl. S.F.1⁵ ¶¶ 3-4.) An intermittent catheter is used to drain the bladder for a specific purpose, e.g., a surgical procedure, and lacks an inflatable balloon.⁶ (Id. ¶ 2; Pl. S.F. ¶ 10.) A Foley catheter remains in the urethra for longer periods of time, allows for continuous drainage of urine, and has an inflatable balloon that holds the catheter in the bladder. (Pl. S.F. ¶ 11; B. S.F. ¶ 2.) "[A]n infection control Foley catheter is a standard Foley catheter that has been coated or impregnated with antimicrobial agents to prevent the colonization of bacteria on the catheter's surface," thereby reducing the chances of the patient developing a urinary tract infection ("UTI"). (Pl. S.F. ¶ 11; B. S.F. ¶ 3.)

Catheters are made from silicone or latex. Silicone catheters tend to be higher priced than latex ones, although silicone catheters are going down in price. (Pl. Ex.-2, 170 at 344-45.) Silicone catheters also tended to be rougher than latex, possibly causing trauma on insertion and needing a coating to make the catheter easier to insert. (Id. at 345.) Newer silicone catheters are smoother and closer in feeling to latex. (Id.) Latex catheters drain the bladder faster than silicone ones. (Pl. Ex.-1, 171 at 56.)

⁴"S.F." refers to a party's Statement of Uncontroverted Material Facts and is cited only when the referenced fact is undisputed by the opposing party or when the dispute is not germane or genuine.

⁵"Pl. S.F.1" refers to St. Francis' Statement of Uncontroverted Material Facts submitted in support of its response to Bard's motion for summary judgment. "Pl. S.F.2" refers to St. Francis' Statement of Uncontroverted Material Facts submitted in support of its motion for partial summary judgment.

⁶There are also specialty catheters that are primarily used in operating rooms. (Pl. Ex.-2, 143 at 21.)

St. Francis is a medium-size hospital with 258 licensed beds and a large volume of surgery. (B. S.F. ¶ 26; Pl. Ex-2,⁷ 33 at 26.⁸) Although St. Francis does not have to join any Group Purchasing Organization ("GPO"), it is a member of two – MedAssets and Novation – and has been for at least seven years. (Id. at 27-28, 35, 74.) It purchases its medical supplies through Novation and its pharmaceuticals through MedAssets. (Id. at 33.)

In its four-count second amended complaint,⁹ St. Francis, acting in its own behalf and in behalf of the members of two defined classes,¹⁰ alleges that certain conduct of Bard is an

⁷"Pl. Ex-2" refers to the exhibits submitted by St. Francis in support of its statement of genuine issues in response to Bard's motion for summary judgment. "Pl. Ex-1" refers to exhibits in support of St. Francis' statement of uncontested material facts submitted in response to Bard's motion for summary judgment.

⁸Both parties submitted volumes of exhibits, including, but not limited to, pages of depositions, company documents, contracts, studies, declarations, and expert reports. Some exhibits were submitted by both parties; some were submitted more than once by the same party. For instance, St. Francis' exhibit 2 is the same as Bard's exhibit 128. St. Francis' exhibit 178 is the same as its exhibit 111. The Court will cite such duplicative exhibits by reference to only one location. The citation to one party's exhibit and not to the duplicative exhibit submitted by the opposing party is not to be misinterpreted as any preference for one party or the other. Additionally, many of the deposition pages submitted by both parties are from another case, Rochester Medical Corp. v. C.R. Bard, Inc., No. 5:08-CV-060 (E.D. Tex.).

⁹St. Francis voluntarily dismissed a fifth count for civil conspiracy.

¹⁰There is a nationwide class and a Missouri sub-class. They are defined as follows.

I. Nationwide Class

All persons or entities who purchased Urological Catheters in the United States directly from Bard at any time during the period February 21, 2003, through the present and whose purchases of Bard's Urological Catheters were governed by Bard's contracts with GPOs. Excluded from the Class are: Bard's parents, subsidiaries, affiliates, and agents; distributors; and federal governmental entities.

II. Missouri Sub-Class

All persons or entities in the State of Missouri who purchased Urological Catheters in the United States directly from Bard at any time during the period February 21, 2003, through the present and whose purchases of Bard's Urological Catheters were governed by Bard's contracts with GPOs. Excluded from the Class are: Bard's parents, subsidiaries, affiliates, and agents; distributors; and federal governmental

unreasonable restraint of trade, in violation of § 1 of the Sherman Act, 15 U.S.C. § 1 (Count I); is an impermissible monopoly, in violation of § 2 of the Sherman Act, 15 U.S.C. § 2 (Count II); is exclusive dealing, in violation of § 3 of the Clayton Act, 15 U.S.C. § 14 (Count III); and is in violation of Missouri's Antitrust Law, Mo.Rev.Stat. § 416.031 (Count IV). St. Francis moves for partial summary judgment on whether Bard's GPO contracts have an anticompetitive effect and, alternatively, whether it may be inferred that Bard has market power over Foley catheters sold through GPOs. Bard moves for summary judgment on all issues. Both parties have submitted voluminous material.¹¹ Some the Court finds to be irrelevant; and, as noted above, some is duplicative. The material found by the Court to be relevant is set forth below.

GPOs. A GPO is a purchasing intermediary that negotiates contracts for medical supplies on behalf of its member hospitals. (B. Ex-2, 21 at 20; Pl. Ex.-1,¹² 89 at 1.) Hospitals voluntarily belong to GPOs to obtain (i) better prices¹³ and services from the vendors on contract, (ii) lower expenses associated with having to negotiate and administer purchasing contracts, (iii) assistance with resolving product failures, and, (iv) sometimes, results of the GPO's investigations and assessments of various products. (B. Exs.-2, 15 at

entities.

¹¹Specifically, St. Francis submitted 13 volumes with an approximate average of 500 pages per volume. Bard submitted 7 volumes.

¹²See note 7, *supra*.

¹³Indeed, Bard had to lower its prices for urological products after GPOs became a force in the marketplace. (B. Ex.-2, 61 at 33.)

263-64; 27 ¶¶ 14, 15; 28 ¶¶ 20-21; 31 ¶¶ 19, 22, 23; 33 at 35; 34 ¶¶ 5-7; 38 at 54; 39 at 11; 43 at 8; 49 ¶ 13-13; 58 ¶¶ 13-19; 81 ¶ 21; Pl. Exs.-1 149 at 124, 198 at 137.) GPOs also allow a hospital to take advantage of the GPO's training programs on new products. (B. Ex.-2, 49 ¶ 14.) Prices on GPO contracts have generally gone down each year. (B. Ex.-2, 7 at 430.) "On average, hospitals buying under the challenged GPO contracts pay sixteen percent less than hospitals not buying under contract." (B. Ex.-2, 21 at 9.) Mike Brown, director of materials management at University Hospital, testified that GPOs give the hospital access to greater purchasing power and better pricing and reduces their staffing needs. (Pl. Ex.-1, 158 at 57.) William Tegel, director of material management at St. Francis, testified that St. Francis purchases between 10,000 and 20,000 products each year from approximately 1000 vendors. (B. Ex.-2, 33 at 38.) Individual negotiations with vendors would be prohibitively time consuming, although the prices would probably be better. (Id. at 39.) Plus, using a GPO, one purchasing order could be issued where without it 150 to 200 purchasing orders would be required. (Id. at 78.) And, he would have to add a full-time employee if he wanted to buy everything directly from the manufacturers. (Id.)

GPOs are also helpful in establishing the market price for a particular product and in establishing a starting point for negotiations for lower-priced commodity products. (B. Exs.-2, 33 at 40; 41 at 176; 81 ¶ 21.) One GPO, Novation, has helped its members negotiate local agreements with vendors under its contract. (B. Ex.-2, 81 ¶¶ 7-9.) A GPO is particularly useful to small hospitals in getting lower prices.¹⁴ (B. Exs.-2, 27 ¶ 13; 28 ¶¶ 18-19; 31 ¶ 21;

¹⁴The materials manager for one hospital, Indian River Medical Center, estimated in 2006 that the Center saved three to five million dollars a year by belonging to a GPO. (B. Ex.-2 153 at 16.)

152 at 15.) Robin Hanson, a vice-president of sales for Bard, testified that small hospitals tended to be compliant with GPO agreements. (B. Ex.-2, 11 at 751.) And, as exemplified by St. Francis, hospitals can often belong to more than one GPO¹⁵ and often switch from one GPO to another. (B. Exs.-2, 16 at 16; 31 at 7; 36 at 19; 37 ¶ 5; 39 at 71; 40 at 62; 42 at 14-15; 43 at 65; 119 at 93.) See also Bard's Exhibits-2, 119; 157 at 34 (Ochsner Health System switched from Novation to MedAssets because it made more sense).

It is estimated that 96 to 98% of all hospitals are members of GPOs. (Pl. S.F.1 ¶ 23.) In 2002, 85% of all hospital purchases nationwide were through the seven largest GPOs. (B. Ex.-2, 21 at 21.) Of those seven, Novation and Premier are the largest. (B. Exs. 15 at 38, 43 at 8.) From 2003 to 2008, 65% Bard's total sales of urological products were pursuant to Novation and Premier GPO contracts. (B. Ex.-2, 21 at 58-59.) Novation includes a provision in all its supply contracts that the agreement does not constitute a commitment to purchase any of the products. (B. Ex.-2, 43 at 67, 68.) A January 2005 document indicated that Novation purchased approximately one-third of the market in urological products. (Pl. Ex.-2, 133 at 109.)

Every GPO asks for a dual source and sole source bid. (B. Ex. 7 at 310.) Whether the contract for a particular product category, e.g., urological products, is to be a sole source, dual source, or multi-source agreement is decided by the GPO. (B. Ex. 32 at 60.) Bard does not have any control over the question.¹⁶ (*Id.*) Prices under sole source contracts for

¹⁵An exception is the Health Trust Purchasing Group. (B. Ex. 47 at 423.)

¹⁶Plaintiffs submitted evidence that Bard was invited to a meeting of the Novation nursing committee when the committee was discussing Rochester's application to have its Release NF catheter be accepted under Novation's new technology provisions. There is no evidence that Bard controlled the

urological products are 2.3% lower than those on multi-source contracts; prices under dual source are 0.8% lower. (B. Ex.-2, 21 at 69.) Regardless, in January 2007, Premier went with multi-source agreements, including with Bard's competitors, Tyco International (US), Inc. ("Tyco"), Rochester Medical Corporation ("Rochester"), and Hollister. (Pl. Ex.-2, 64.) It is anticipated that Novation will have few, if any, sole source awards in the future. (Pl. Ex.-2, 132 at 101.)

Several of Bard's GPO contracts include a tiered pricing structure. (See e.g. B. Ex.-1, 6; B. Ex.-2, 54.) Tier pricing gives GPO members who are committed to a product line lower prices.¹⁷ (B. Ex.-2, 14 at 147.) "[C]ommitment 'tiers' . . . give hospitals the opportunity to choose higher levels of discounts in exchange for higher levels of commitment." (B. Ex.-2, 21 at 36.) Even at the most committed GPO contract tier, however, a hospital is not required to commit 100%. (B. Ex.-2, 21 at 24, 56.) Rather, the typical most-committed tier requires a 85% share and a commitment for five out of six product categories. (Id. at 47.) Even so, a hospital on a tier three GPO contract with Bard could elect to purchase all its urological products from another manufacturer. (B. Ex.-2, 58, ¶ 6, 7.) For example, Indian River Medical Center purchases urological products from Bard under a Premier contract. (B. Ex.-2, 31 at 8.) That contract provides that the Center must purchase 85% of its general urological requirements from Bard to obtain the best prices for

resolution of that application.

¹⁷If a supplier does not have a full line of urological products, the supplier is exempt beginning in April 2005 from Novation's share calculations for purchases under the various tiers and in March 2007 from Premier's calculations. (B. Ex.-2, 21 at 58.)

those products. (Id. at 9.) John Walker, the Center's materials management director, testified in his deposition that the Center is not forced to buy any of Bard's products. (Id.) Indeed, it purchases intermittent catheters from Medline pursuant to a local agreement and drainage bags for Foley catheters from Tyco. (Id. at 9-10.) Additionally, access tiers permit members who do not want to purchase in bulk from a supplier to still purchase some products under the GPO contract. (Pl. Ex.-2, 170 at 363-64.)

Contracts with no alternative commitment or price levels, i.e., contracts with "one" tier, represent 31.8% of Bard's GPO sales. (B. Ex.-2, 21 at 55.) In Bard's two-tiered contracts, 34.4% of its sales are in the first, or lower-commitment, tier, although the most committed tier carries a 5.3% discount for relevant products. (Id.) In Bard's three-tiered contracts, 70.6% of its sales are in the two tiers that require the lower commitments, although the most committed tier carries a 15.3% discount for relevant products. (Id.) This third tier can require that 85% or greater of aggregate annual requirements in eight categories be purchased. (B. Ex.-2, 69 Ex. A; Ex.-2, 116.) In Bard's four-tiered contracts, 44.9% of its sales are in the three tiers that require the lower commitments, although the most committed tier carries a 32.9% discount for relevant products. (B. Ex.-2, 21 at 55-56, 70.) This fourth tier can require that 80% of a member's purchases be in four out of seven product categories offered by Bard. (B. Ex.-2, 54.)

A GPO member may be required to sign a letter of commitment when agreeing to purchase a manufacturer's products pursuant to a GPO contract.¹⁸ For instance, in January

¹⁸A commitment to purchase a certain amount of a manufacturer's products may apparently be renegotiated. For instance, a January 2006 agreement between Broadlane, a GPO, and Tyco reduced the committed level of Broadlane's members from 85% to 60%. (B. Ex.-2, 133.) It also provided

2007, Southeast Missouri Hospital signed a letter of commitment pursuant to the contract between MedAssets, a GPO, and Tyco for urological products. (B. Ex.-2, 134.) A letter of commitment with MedAssets Select Program requires that members select a certain number of products in various categories to get better pricing, e.g., the program requires that 85% of a member's needs from five of six categories of Bard's products be purchased to qualify. (Pl. Ex.-1, 154 at 35-37.) Bard uses letters of commitment to track the GPO under which a hospital is making their purchases. (Pl. Ex.-2, 160 at 160.)

Some GPO contracts provide for "share-based discounts" based on a manufacturer's share of a customer's purchases of its products under contract. (B. Ex.-2, 21 at 27.) Some provide for "bundled-share discounts" that give greater discounts for customers if they maintain a certain level of purchases in several of a manufacturer's product categories.¹⁹ (B. Ex.-2, 21 at 27.) The most prevalent level in Bard's bundled-share contracts is 85%. (Id.) GPO contracts providing for share discounts, whether bundled or not, allegedly benefit the seller by providing for incremental sales and the buyer by providing for "enhanced discounts." (B. Ex.-2, 21 at 32.) "The seller offers a discount and the buyer commits to

that the supplier would pay Broadlane's administrative fees of 3% of the aggregate purchase price paid during the prior calendar month by all customers for all products purchased under the agreement, less any credits and rebates. (Id.)

¹⁹For instance, Bard's 2007 urological products agreement with Broadlane required at least 85% of a member's annual aggregate purchases, measured in terms of dollars, for the best prices. (Pl. Ex.-2, 66.) If a member was not compliant, the member would be moved to an access tier and its rebates suspended. (Id. at 4.) The rebates would be later reinstated should its purchases subsequently satisfy the committed level. (Id.) But see note 18, *supra*.

buying more than he otherwise would at the discounted price." (*Id.*) Additional discounts may be achieved through sole-source or dual-source GPO contracts. (B. Ex.-2, 21 at 29.)

Also, some GPOs include a "most favored nation" clause requiring that the supplier not give a better price to another GPO. (B. Ex.-2, 171 at 158.) The clauses compare like GPO contracts to like GPO contracts in terms of aggregate value. (Pl. Ex.-1, 153 at 58.) Bard's last renewals of GPO contracts did not include such clauses. (Pl. Ex.-2, 132 at 119.)

Either party to a GPO contract may terminate it without cause after giving the notice required by that contract. (B. Ex-1,²⁰ 6; B. Exs.-2, 69, 78, 80, 84-87, 93, 95-98, 100-01, 103-05, 108, 111; (Pl. Ex.-2, 87.) In some contracts, that requirement is 60 days' notice, in others it is 90 days. (*Id.*)

Although the majority of hospitals do purchase medical supplies through GPOs, they do not have to do so. (B. Ex. 7 at 262.) Membership in a GPO does not require that all applicable purchases be made through that GPO,²¹ including those purchases that are covered under a sole source contract. (B. Exs.-2, 24 at 392; 42 at 14; 43 at 76-77; 49 ¶ 6; 58 ¶ 7; 106 at 230; Pl. Exs.-1, 164 at 66-67; 169 at 15, 87; 172 at 16.) Although Bard has a GPO contract with Novation, some of Novation's members contract with Bard independent of the GPO contract. (B. Ex.-2, 47 at 390.) For example, St. Francis is a member of Novation,

²⁰See note 3, *supra*.

²¹The Court notes that Premier's 2002 group purchasing policy setting forth the guidelines for its Commitment Program expressed a preference that its members not "independently solicit quotations from suppliers for products or services covered under [the Program] agreements . . ." (Pl. Ex.-2, 115 at [4].) It was anticipated that the highest level of commitment would be less than 100% "to allow members to meet unique needs or undertake trials of newly emerging products promising advantages." (*Id.*)

however, Tegel will negotiate his own contract if he does not like a vendor on a GPO contract or if he feels that the GPO's vendor's product is inferior, as do the procurement managers for Ochsner Health Systems and Memorial Hermann Healthcare Systems. (B. Exs.-2, 33 at 56, 59; 39 at 13; 37 ¶¶ 12-13.) When another GPO, Broadlane, switched from a dual source contract with Bard and Tyco to a sole source contract with Bard, the Manatee Health System continued to purchase from Tyco, but did so under a local agreement. (B. Ex.-2, 27, ¶ 9.) And, as noted, health care facilities with a GPO contract make purchases not covered by that contract. For instance, the University of Virginia Medical Center buys 35 to 38% of its products from suppliers who are not under any GPO contract, including purchasing male external catheters from Rochester. (B. Ex.-2 16 at 19-20.) If it does not feel that its GPO, Novation, is giving value, it can switch to, or join, another GPO. (Id. at 16.) If a clinician thinks another product would improve patient care, the product can be evaluated regardless whether it is under a GPO contract. (Id. at 17.) Its purchasing department does not veto a clinician's decision about medical products. (Id.) The Manatee Health System purchases 20% of its products without a GPO contract, some of which purchases are due to a preference or better prices; the Crozer-Keystone Health System purchases 30-35% of its products without a GPO contract; the Indian River Medical Center purchases approximately 40-50% of its supplies without a GPO contract, including when there is a new product; and the Wadley Regional Center purchases approximately 32% of its medical supply products outside its GPO contracts. (B. Exs. 27 ¶¶ 9-10; 28 ¶ 11; 31 ¶ 18; 49 ¶ 6; 153 at 16-17.) Similarly, members of another GPO, Health Purchasing Group ("HPG"), are not barred from purchasing urological products from other than Bard although

Bard has a sole source agreement with HPG. (B. Exs.-2, 59, ¶¶ 2, 4, 5; 163 at 21, 63.) If they chose to do so, the non-Bard agreement would be independently negotiated by the member. (B. Ex.-2, 163 at 21.) HPG does expect, however, that members will make their urological product purchases from Bard – that is why they join a GPO. (B. Exs.-2, 59, ¶ 7; 163 at 58, 61; B. Ex.-2, 145 at 56, 58.)

From 2002 to 2008, "most sales of urological products were to facilities that purchased from more than one supplier." (B. Ex.-2, 21 at 42.) For intermittent catheters, the percentage varied between 68.8% to 80.5%. (Id.) For Foley catheters, the percentage varied between 56.8% to 74.7%. (Id.) Between 2003 and 2007, the percentage of sales to facilities that purchased from four or more suppliers exceeded 15% annually for intermittent products and 10% annually for Foley products. (Id.) During this same time period, "roughly 30 to 40 percent of Bard's sales of relevant products were made outside of GPO contracts." (Id. at 45.)

A GPO member purchasing off-contract may have to pay an increased price. (B. Ex.-2, 14 at 144-45.) Mike Brown testified that there were economic incentives for University Hospital to buy products on a GPO contract. (Pl. Ex.-2, 135 at 148.) Nothing in its Novation contract, however, prevented the hospital from buying off-contract but for the loss of rebates²² and the possibility of losing the tier pricing associated with a certain level of purchases. (Id. at 210-11.) Indeed, he sometimes buys products off-contract that are more expensive than those that are. (B. Ex.-2, 41 at 68, 175-76.) Novation has no recourse if he

²²Bard pays a rebate off any contract, regardless of whether it is a GPO, IDN, or individual contract. (Pl. Ex.-2, 157 at 85.)

buys off-contract, nor is there any penalty or sanction if he does not buy a certain percentage of product from Bard. (Id. at 74.) See also Bard's Exhibits-2, 114 at 96 (no penalties or sanctions were assessed against University of Utah Hospitals when bought off Novation contract); 42 at 110 (same as to Crozer Keystone).

GPOs do not purchase or distribute the products. (B. Exs. 5 at 333; 15 at 27; 43 at 63.) Rather, the hospital purchases the products from the supplier or from a distributor. (B. Ex. 43 at 64, Ex.-2, 135 ¶ 3.) The GPO awards the distribution contracts. (B. Ex. 25 at 201.)

GPOs do get paid by the suppliers a corporate dividend, or administrative fee, a portion of which is returned to the member.²³ (B. Ex.-2, 51 at 38.) Mark McKenna, the president and chief executive officer of Novation, testified that a GPO gets paid an administrative fee by a manufacturer based on what a member decides to purchase. (B. Ex.-2, 43 at 23.) Those fees have gone down in the past few years. (Id. at 24, 85.) A hospital may also receive a rebate. The president of Bard, Robert E. Anderson, describes rebates as delayed price decreases. (B. Ex.-2, 25 73.) They are returned to the hospitals and are not retained by the GPOs. (Id.)

²³For instance, HPG receives a 3% administrative fee under Bard's urological products contract. (Pl. Ex.-2, 145 at 52-53.) Under that same contract, Bard pays a 2.5% rebate, which is allocated to the various hospitals that purchased the products. (Id. at 54.) Also, in response to an e-mail about formulating a proposal for a group of Novation members that had decided to form their own, a Bard officer noted that Bard paid fees to Novation because Novation's size and ability to move a large market share with a sole-source agreement relieved Bard from having to invest additional selling resources. (Pl. Ex.-2, 57.)

When inviting manufacturers to bid, Novation includes in its supplier profile requests for information on a company's annual domestic sales for the products in question and its market share, although a manufacturer's market share is not part of Novation's decision criteria award matrix.²⁴ (B. Exs.-2, 43 at 79; B. Ex.-2, 66 at 492, 495.) When deciding whether to award a supplier a contract, Novation employs a decision criteria award matrix with both financial and non-financial criteria. (B. Ex.-2, 62 at 12.) Pricing is one-half the outcome result; the non-financial criteria is the second half. (Id. at 15, 51.) If a supplier meets the minimum acceptable score on the non-financial criterion, then the financial portion is analyzed. (B. Ex.-2, 50 at 31.) Included in the questions relevant to the non-financial criteria are such requests as whether there are both silicone and latex products (relevant to the breadth and depth criterion) and how many field representatives the company has (relevant to the ability to supply and service the products and to conversion assistance). (B. Ex.-2, 66 at 499-501.) And, when Novation invited suppliers to bid on a GPO contract for urological products, it asked for a profile of the company, including the number of sales representatives, the list of manufacturing facilities, the identification of products that are not self-manufactured, the amount of its sales, a list of its other GPO contracts, its method of distribution, and the percentage of the company's acute care business compared to its non-acute care business.²⁵ (B. Ex.-2, 154.) It also asked about product safety. (Id.) Rochester

²⁴On the other hand, Premier considers a supplier's market share as an indicator of which products their members preferred to buy. (Pl. Ex.-2, 159 at 60.) Consequently, market share was a consideration in deciding whether to award a supplier a contract. (Id. at 59.)

²⁵The United States market is divided into acute care and extended care markets. (Pl. Ex.-2, 44.) Acute care markets include hospitals, surgery centers, and outpatient clinics. (Id.) Extended care

reported that its products and packaging were latex-free. (Id.) Its acute care business was 5%; its non-acute care was 95%. (Id.)

The Novation Nursing Clinical Practices Council ("the Council") assesses the non-financial criteria of the various bids and scores suppliers. (B. Exs.-2, 42 at 70-72; 50 at 30; 62 at 13.) For instance, when deciding to award a contract for urological products, the Council scored the bids of four manufacturers by factors of clinical acceptability, breadth of product line, ability to supply, and conversion assistance. (B. Ex.-2, 42 at 70-72.) Lynda Bailey served on the Council and testified that of the four non-financial criteria, the most important was clinical acceptability and then, in order of diminishing importance, breath and depth, ability to supply and service, and conversion assistance. (B. Ex.-2, 114 at 39-40.) When the Council scored the bidders for the decision criteria award matrix, they did not consult with anyone, including anyone from Novation or Bard. (Id. at 91.) She did not consider whether a bidder was on a GPO contract. (Id. at 92.)

In the December 2004 matrix, Bard had a score of 905, Tyco of 885, Rochester of 719, and Medline of 7691. (B. Ex.-2, 42 at 70-72.) Bard's average score for clinical acceptability was 322, Tyco's was 301, and Rochester's was 258. (Id. at 112-13.) For breath and depth, Bard's score was 281, Tyco's was 275, and Rochester's was 215. (Id. at 114.) For ability to supply, Bard's score was 186, Tyco's was 181, and Rochester's was 123. (Id.) See also Bard's Exhibit-2, 130 (listing non-financial criteria for interventional urological products

markets include nursing homes, rehabilitation and long-term care facilities, home health care agencies, and physician offices. (Id.) Acute care sales represent 37% of Bard's total units sold and 48% of total dollars. (Id.)

and summarizing committee members' assessment of scores for seven manufacturers, including Bard, Tyco, Rochester, and Medline). An asset of Bard's in 2004 was its four manufacturing facilities. (B. Ex.-2, 66 at 551, 555.) Three of the four bidders submitted multi-tier pricing; Rochester did not. (B. Ex.-2, 50 at 95.) The Council evaluated sole source, dual source, and multi-source bids. (B. Ex.-2, 62 at 133.) Bard gave the best pricing for a sole source contract and ranked the highest on non-financial criteria. (Id. at 133-34.) Although the Council can add additional awardees to a GPO contract, the Council voted to award Bard a sole source contract for acute care urological products. (B. Exs.-2, 42 at 115; 50 at 40.)

The Novation 2005 agreement for urological products awarded a sole source agreement to Bard for urological catheters and related accessories and a multi-source agreement to Bard, Cook, and Boston Scientific for interventional urology. (Pl. Ex.-2, 175 at 5.) For the first category, Bard had a score in non-financial criteria of 905, Tyco of 885, and Rochester of 719. (Id. at [10].) Bard included an access tier for all members. (Id. at 5.)

Anthony Trupiano, a vice-president of material management for SSM Health Care, was, at the time of his deposition in May 2006, on the committee for Premier that reviews products. (B. Ex.-2, 35 at 9, 19.) The committee has included in its recommendations vendors that are not recommended by Premier and has excluded ones that are, including a recommendation that Bard receive a sole source contract for its dialysis catheter. (Id. at 28, 30.)

During the class period, 58.3% to 66.9% of Bard's total sales of intermittent and Foley catheters were through GPOs and 12.9% to 16.6% were with no contract. (B. Exs.-2, 21 at

24; 25 at 201.) From 2003 to 2008, between 33.1 and 41.7% of Bard's sales of the relevant product were not covered by GPO contracts. (B. Ex.-2, 21 at 105.) The GPO contracts vary; some are sole source, some are dual, and some are multi-source. (See B. Exs.-2, 4 (listing type), 6 (sole source), 8 (multi-source), 32 at 70-72 (sole source with Novation; multi-source with MedAssets; Pl. Ex.-1 203 (dual source with Consorta)). There is "fierce competition" for sole source contracts. (B. Ex.-2, 11 at 732.) Bard and other manufacturers offer more aggressive pricing for a sole source contract. (B. Exs.-2, 7 at 735; 25 at 71.) Even so, Bard does not expect that 100% of a hospital's product needs be purchased under a GPO contract, including a sole source contract. (B. Ex.-2, 32 at 186.) Indeed, for the period from 2003 to 2008, Bard's competitors accounted for 8.9% of Foley product sales to GPO members with sole source contracts with Bard, 13.9% to members with dual-source contracts, and 14.3% to members with multi-source contracts. (B. Ex.-2, 21 at 46.)

As noted above, hospitals may purchase urological catheters from Bard directly or from a distributor. (B. Ex.-2, 135 ¶ 3; Pl. Ex.-2, 157 at 22.) The majority use a distributor of their choosing.²⁶ ²⁷ (B. Ex.-2, 135 ¶ 4; Pl. Ex.-2, 157 at 20.) There are two separate transactions in such cases. (B. Ex.-2, 135 ¶ 4.) A distributor buys the product from Bard at list price. (*Id.*) The hospital buys the product from the distributor at the contract price plus

²⁶Thus, Bard's sales force calls on hospitals, not GPOs or distributors. (Pl. Ex.-2, 157 at 26-27.)

²⁷For instance, when considering whether to buy a particular product, Daniel Humphrey, Memorial Hermann Healthcare System's chief supply chain officer, looks at, among other things, a supplier's manufacturing capabilities, back order problems, product performance, patient safety, and ability to contract with the System's distributor. (Pl. Ex.-2, 149 at 42, 44.) The latter is important because they use their distributor as a warehousing agent; therefore, they would house their product elsewhere if the supplier had no contract with their distributor. (*Id.* at 43-44.)

the distributor's mark-up. (Id.) Pricing is not negotiated with distributors. (Pl. Ex.-2, 157 at 20.) The contract price is the price that Bard has agreed to under a contract that the hospital has use of, e.g., a GPO contract. (Id.) The amount of mark-up varies according to negotiations between the distributor and the hospital. (Id.) Bard has no role in these negotiations. (Id. ¶ 5.) The hospital pays the distributor; the distributor negotiates shipping terms, ships the product, invoices the hospital, and collects the payment. (Id.) See also Plaintiffs' Exhibit-2, 157 at 39, 83-84. "Most of the time, hospitals purchase Bard's catheters from distributors at a price that is below Bard's list price . . ." (B. Ex.-2, 135 ¶ 6.) "When that happens, the distributor obtains a rebate from Bard to account for the difference in price between the contract price the hospital paid the distributor and the list price the distributor paid Bard." (Id.) Bard began phasing out distributor-agency agreements in 2004 and now uses a distributor rebate agreement. (Id. ¶¶ 9-10; B. Ex.-2 189 ¶ 3.) See also Plaintiffs' Exs.-2, 59-60 (copies of Bard's distributor rebate agreements, and 61, a distributor agency agreement).

The Products. Bard introduced the first infection control latex Foley catheter in 1994. (B. S.F. ¶ 3.) Rochester introduced its silicone infection control Foley catheter in 1998. (B. S.F. ¶ 4.) Tyco introduced its infection control Foley catheter in 2003. (Id.) Other infection control Foley catheters have been introduced by Cook Urological (Spectrum, a silicone, antibiotic coated catheter) and Medline (SilverTouch, a silver coated catheter). (Id.; B. Ex.-2, 8) Infection control Foley catheters are the largest selling Foley catheter. (B. Ex.-2, 21 at 15.) "[F]rom 2002 to 2008, the number of suppliers of Foley catheters to hospitals was

never less than eight (in 2004) and had increased to thirteen in 2007 and 2008." (B. Ex.-2, 21 at 42.)

Bard uses several different types of coatings on its catheters: a hydrogel compound; silicone, including a silicone hydrophilic silver coating, such as used on Lubri-Sil I.C.; and a combination of silver and hydrogel, such as used on Bardex IC. (B. Ex-2, 2 at 75-76; Ex.-2, 23 at 25-26.) Rochester's Foley catheter, Release NF, incorporates nitrofurazone. (B. Ex.-2, 17 at 7.) Nitrofurazone is a preventive, anti-bacterial agent, not a treatment for infections. (Id.; B. Ex.-2, 169 at 188.) Its "kill mechanism is different than that of antibiotics." (B. Ex.-2, 174.)

Although the Release NF catheter was initially submitted without any infection-control claims so that it could be evaluated by the Food and Drug Administration ("FDA") as a substantial equivalent to an existing product, after January 1998 Rochester can claim that the Release NF reduces UTIs. (B. Exs.-2, 10 at 35; 13 at 24-25; 23 at 98-99.) Bard can also make such claims. (B. Ex.-2, 23 at 98-99.) Tyco cannot. (Id.) Tyco was informed by the FDA in 2006 that it could not market its Dover Silver catheter as reducing UTIs. (B. Exs.-2, 7 at 4; 21 at 18-19.)

The 510(k) review process²⁸ governs approval by the FDA of a device that is substantially equivalent to one that is already on the market. (B. Ex.-1, 10 at 30.) The filing

²⁸"[T]o receive 510(k) clearance, a manufacturer must give the FDA 90 days' notice that the manufacturer intends to market a medical device (1) which is substantially equivalent to a device already approved by the FDA, and (2) which has the same intended use as the approved device." **Biomedical Sys. Corp. v. GE Marquette Medical Sys., Inc.**, 287 F.3d 707, 708 (8th Cir. 2002) (per curiam). "A substantially equivalent device is examined in the § 510(k) process only for similarities with existing devices; safety and effectiveness are not the focus." **Brooks v. Howmedica, Inc.**, 273 F.3d 785, 794 (8th Cir. 2001).

fee for such review in 2008 was \$3,404 (50% less if one qualifies as a small business with gross receipts or sales of no more than \$100 million).²⁹ For such review, performance data is usually required, but clinical data is not. (Id.)

Because of concerns about latex allergies, Bard is trying to improve its silicone catheters.³⁰ (B. Ex.-2, 3 at 88.) As of February 2006, approximately 6% of the market for catheter products was for silicone. (B. Ex.-2, 4 at 384.) Bard's Lubri-Sil I.C. is a silicone infection control catheter. (Id. at 93.)

Under the theory that the lack of a GPO contract was an obstacle to Rochester having the opportunity to commercially take advantage of product improvement and increase its revenue, Rochester applied to Novation to have Release NF added to contracts as new technology. (B. Exs. 12 at 261, 63 at 15; Pl. Ex.-2, 165 at 75.) Novation makes a decision on whether to accept or reject a new technology application based on the recommendations of its members. (Pl. Ex.-2, 131 at 64.) For a product to qualify as such, it "must be innovative and offer substantially improved benefits over what already exists." (Id. at 83.) The clinicians on the Council, not Novation, made the decision not to add Release NF to the contract for urological products. (B. Ex.-2, 63 at 16; Pl. Ex.-2, 165 at 75.) They decided Release NF did not meet the criteria for evaluation as new technology and that there was insufficient evidence to support Rochester's claims of increased patient care benefits from

²⁹See Food and Drug Administration, Comparison of Quantitative Decision Goals in MDUFMA I and II, [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/Medical Device UserFeeandModernizationActMDUFMA/ucm109319.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109319.htm) (last visited Sept. 11, 2009).

³⁰In January 2004, Tyco's estimated share of the silicone-coated catheter market was 65%; Bard's was 35%. (B. Ex.-2, at 95.)

the nitrofurazone. (B. Exs.-2, 63 at 17; 177.) They based their decision on the information supplied by Rochester and had not actually used the products. (B. Exs.-2, 63 at 18; 178 at 49.) They did not base their decision on market share. (B. Ex.-2, 63 at 34.) Had they felt it necessary, they would have consulted a urologist or other physician about the Release NF. (Pl. Ex.-2, 165 at 79-80.) If a request had been made that the users of Release NF – Rochester had provided a list of 31 clinical users – be contacted, they would have been. (B. Exs.-2, 176; 178 at 70-71.)

In a three-year period, Novation awarded over 50 contracts for innovative technology. (B. Ex.-2, 43 at 42.) Some of the winning companies have small market shares. (Id. at 80.)

Regardless of whether a new technology application is granted, because Novation is a voluntary GPO, its members can purchase any product they chose; however, they might not be able to do so at the same price as under the GPO contract. (Pl. Ex.-2, 131 at 78, 84.) Indeed, in 2006, a hospital with a Novation contract could purchase all its silicone catheters needs within the 15% headroom in the contract and retain the pricing tier with the lowest prices. (B. Ex.-2, 4 at 384-85.) The Crozer-Keystone Health System, under a Novation GPO contract, will purchase products they consider to be superior regardless of whether the product is under the contract. (B. Ex.-2, 28 ¶¶ 10, 12.)

The other of the two largest GPOs, Premier, had a four-stage process for the evaluation of technology breakthrough submissions. (Pl. Ex.-2, 186 at 4.) When presented with Rochester's submission for the Release NF, Premier noted that studies had shown that nitrofurazone-impregnated catheters were significantly more effective than conventional Foley catheters in reducing catheter-associated UTIs, but no "well-designed studies" had

compared the nitrofurazone-impregnated Foley catheters to silver-coated ones. (Id. at 5-6.) Premier recommended to its nursing committee that the technology breakthrough clause not be invoked because the Release NF did not offer significant advantages over other infection control catheters currently offered on GPO contracts, members could purchase Release NF off-contract,³¹ and, if Premier wanted, a GPO contract could be entered into with Rochester without invoking the clause. (Id. at 7.) The Premier Nursing Council concurred and additionally found that comparable products were available through existing agreements with Bard and Tyco. (Id.; B. Ex.-2, 179.)

Rochester's 10-K report for the period ending September 30, 2007, noted that Rochester had a GPO contract with Premier, effective March 1, 2007, and an innovative technology contract with Novation, effective September 1, 2007. (B. Exs.-2, 17 at 9; 56 at 5.) Rochester's net sales increased in 2008; its net income decreased due to an increase in its marketing and sales budgets and to the 2007 income figure including the proceeds from the settlement of its anti-trust suit, see note 8, *supra*. (B. Ex.-2, 17 at 38, 48.) Additionally, it was reported during a fourth quarter earnings conference call in 2008 that hospitals were "showing very strong interest" in Rochester's infection control catheter. (B. Ex.-1, 13 at 3.) Advanced sales of such catheters had increased by 58% that quarter and by 38% for the year to date. (Id. at 6.) The sales of Foley catheters had increased by 41% for the quarter and by 52% for the year. (Id.) It was further reported that a number of evaluations of Rochester's Foley catheters were underway. (Id. at 19.)

³¹For instance, Indian River will buy new technology products off-contract. (Pl. Ex.-2, 172 at 17.) A resource committee evaluates new products presented to it. (Id.)

In the United States market, Rochester sells only silicone-coated Foley catheters. (B. Ex.-2, 19 at 72-73.) See also Bard's Exhibits-2, 107, 108 (noting that Rochester's GPO contracts with Novation and Premier were for its all-silicone Foley catheters). And, it has only one production line for Foley catheters. (B. Ex.-2, 56 at 5.)

The Competition. A 2001 report by the firm of Frost and Sullivan on the United States Urological Devices Market notes that at least seven manufacturers in the United States market intermittent catheters, the top three of which had a 91% market share. (Pl. Ex.-2, 102 at 3-36, 3-40.) The largest in terms of revenue were Mentor and MMG Healthcare. (Id. at 3-40.) These two companies and Bard comprised the first tier of competition. (Id.) Bard was third with 11% market share. (Id. at 3-41.) Rochester, Coloplast, Tyco, and Cook Urological were the second tier. (Id. at 3-40.) The report further concluded that entry into the market was limited due to the presence of "a couple of dominant players that are well established with broad product offerings." (B. Ex.-2, 22 at 1.) Those players were Bard and Kendall, a subsidiary of Tyco. (Id.)

Bard's market share of urological products varies by such factors as product, time period, contract source and type, and buyer. For instance, Bard attributed the decrease in its market share for urological catheters from \$19.4 million in 1995 to \$15.5 million in 1998 to the shift of health care to out-of-hospital venues. (Pl. Ex.-2, 33.) For the period from 2003 through the second quarter of 2008, Bard had 86.7% of Foley product sales to hospitals and Tyco had 9.7%. (B. Ex.-2, 21 at 16-17.) Bard had a 91.1% share of Foley catheters pursuant to sole source contracts, a 86.2% share of Foley catheters pursuant to dual source contracts, and a 85.8% share pursuant to multi-source. (B. Ex.-2, 21 at 78.) Bard had a

65.7% share of intermittent catheters pursuant to sole source contracts, a 44.9% share of intermittent catheters pursuant to dual source contracts, and a 42.6% share pursuant to multi-source. (Id.) For the period from 2003 to 2006, Bard's revenue share for intermittent products was 34%, Tyco's was 30.3%, and Mentor's was 20.6%. (B. Ex.-2, 21 at 98.) For the period from 2004 to 2008, Bard's share of Foley products sold to hospitals without GPO contracts exceeded its share in hospitals with such contracts. (B. Ex.-2, 21 at 7.) For intermittent products, it did not. (Id.) Bard's 2005 business plan reflected a market share of 51% in acute care urological products. (Pl. Ex.-2, 55.) A marketing plan from that same year listed Bard's market share in Foley and specialty catheters as 82%. (Pl. Ex.-2, 79.) It also noted that concerns about latex allergies were increasing in hospitals. (Id. at 7.) A threat to Bard's position remained the comparison of its latex-free products with those of its competitors. (Id. at 14.) An incomplete line of silicone products remained a weakness of Bard's in 2008. (Pl. Ex.-2, 83.) Plus, an internal Bard January 2003 memorandum reported only a 9.4% reduction in urinary tract infections with the use of Lubri Sil I.C., its silicone Foley catheter. (Pl. Ex.-2, 35.) This rate was not statistically significant. (Id.) A marketing plan issued that same year expressed concern that a negative study at Johns Hopkins Medical Center showing a non-significant 10.3% reduction in catheter-associated UTIs be restricted to Lubri Sil I.C. and not imputed to Bardex IC. (B. Ex.-2, 4 at 7; Pl. Ex.-2, 54.) Bardex IC was 30% of Bard's catheter sales and 24% of the total Foley catheter market. (Pl. Ex.-1, 54.) The plan also noted that Lubri Sil I.C. needed to be improved. (Pl. Ex.-2, 2, 54 at 6.)

Bard has not conducted any head-to-head trials of Release NF against Bardex IC or against Lubri-Sil I.C. (B. Ex.-2, 7 at 34-35.) Anthony Conway, Rochester's president and

chief executive officer, testified that Bard would not participate in head-to-head trials against Release NF, although hospitals wanted them. (Pl. Ex.-1, 162 at 104.) He wanted Bard to support such trials, including financially. (Id.) Although he could have purchased Bardex IC products and have doctors do the study without Bard's formal participation, he did not want to. (Id. at 110.) Rather, he wanted a study supported by both companies. (Id. at 111.) Benson Smith, who retired as Bard's chief operating officer and president in April 1998 and who joined Rochester's board of directors in May 2001, testified in his deposition that he never said that Bard attempted to prevent hospital head-to-head trials of Bardex IC with Release NF. (B. Exs. 9, at 8, 19-20; 12 at 95.) Bard would, however, try to discourage a hospital that it did business with from conducting a competitive evaluation. (B. Ex. 12 at 95.) For instance, Bard would increase its contacts with the hospital or encourage the hospital to contact another hospital that was displeased with the competing product. (Id. at 95-96.) If Bard had a GPO agreement with the hospital, it had "more ammunition" in its efforts because it could "lean" on the hospital and the purchasing agent. (Id. at 97.) Smith also testified that Bard's marketing tactics were aggressive, but customary, when trying to get a hospital to evaluate its products. (Id. at 94.)

Tyco is viewed by Bard as being its biggest competitor. (B. Ex.-2, 24 at 389, 391.) Tyco's Dover Silver is considered to be the first credible threat to Bardex IC. (B. Ex.-2, 4 at 11; Pl. Ex.-2, 56 at 18.) Bard did not, however, lower its prices when the Dover was introduced. (B. Ex.-2, 23 at 100.) Tyco does not have any sole source contracts for its urological catheters, but does sell three urological product lines through dual source contracts. (B. Exs.-2, 15 at 38, 171.) Although Tyco never had a contract with Novation,

10% of Novation members purchase from Tyco and its largest sales dollar base, or 29% of its urological product business, is off-contract in Novation. (B. Exs.-2, 15 at 38, 252; 43 at 78; 62 at 111.) The largest GPO contract Tyco has is with Premier, through which it does 27% of its urological product business. (B. Ex.-2, 24 at 29, 252.)

Another threat to Bard's market share is dual source contracts with GPOs. (Pl. Ex.-2, 34.) Bard's market share depends on whether its GPO contracts are sole source, dual source, or multi-source. As outlined above, Bard's market share decreases according to how many other manufacturers are on the contract, e.g., from a 91.1% share of Foley catheters pursuant to sole source contracts to a 86.2% share of Foley catheters pursuant to dual source contracts, and a 85.8% share pursuant to multi-source.

Another consideration GPOs have when awarding contracts is the manufacturer's ability to supply and service and its conversion assistance. As the Novation supplier profile indicates, the number of field representatives is relevant to these considerations. Bard has a dedicated sales force for urological products of fifty-four people. (B. Exs.-2, 15 at 102; 23 at 9.) In 2004, Bard's business plan included a request for an expanded sales force. (Pl. Ex.-1, 63.) An experienced United States sales force was cited as a strength. (B. Ex.-2, 117 at 7.) It was noted that a competitive loss was worth twice as much as the average conversion to Bard's urological products. (Pl. Ex.-1, 63 at [2].) During the period from September 2002 to January 2005, the marketing department in Bard's Medical Division grew from three people to approximately sixteen. (B. Ex.-2, 24 at 388.) Medline has a sales force of 500 to 600 representatives, sells a full line of urological products, and has contracts with at least six GPOs. (B. Ex.-2, 20 at 23, 25.) In 2003, Rochester had a sales force of six

representatives. (B. Ex.-2, 21 at 65-66.) In its marketing plan for a three-year period beginning in 2003, Rochester listed its primary competitors as Bard and Tyco, noting that both had a large sales force. (B. Ex.-2, 146.) A Premier representative testified in 2006 that she was concerned that Rochester had a sales force of only six people and that its product line was "very clinical" and required clinical support. (Pl. Ex.-2, 170 at 367.) Rochester now has a direct sales force of twelve people. (B. Ex.-2, 17 at 9.)

The relevance of the size of a manufacturer's sales force is reflected in testimony by materials managers for various health care facilities. For instance, the materials manager for Memorial Herman System has never been contacted by a Rochester sale representative, nor did a search of his records reveal any marketing material or requests for product trials by Rochester. (B. Ex.-2, 39 at 38-39.) He considers a manufacturer's sales force disbursement when deciding what products to buy. (Id. at 40.) Mike Brown, director of materials management at University Hospital, never heard of Rochester before Rochester's lawsuit.³² (B. Exs.-2, 41 at 30; 58 ¶ 22.) He was not aware of the Release NF, nor did a search of the records reveal any product information on, marketing material about, or requests for trials of the Release NF. (B. Ex.-2, 41 at 34-35.) Donald Mancuso, the director of material managements for the Manatee Health System, averred that he had never been contacted by any sales representative of Rochester and had never heard of Rochester. (B. Ex.-2, 27, ¶ 16.) The only representatives that have called on Tegel are from Bard and Tyco. (B. Ex.-2, 142 at 112.) See also Bard's Exhibits-2, 42 at 25 (vice-president of Crozer-Keystone Health

³²See note 8, *supra*.

System had never been contacted by Rochester representative); 59 ¶ 10 (director of materials management for Physicians Regional Medical Center had never met Rochester representative or seen Rochester brochure).

Also relevant is whether the product, e.g., Foley catheters, are clinician-preference items or commodities. Novation's Council decided that urological products were not clinical preference products, i.e., products for which physicians, nurses, and other health care providers would have a clinical preference for one product brand over another based on evidence that the preferred product had a favorable impact on patient care. (Pl. Ex.-2, 131 at 80-81.) A hospital may be converted to a different product by selling that product to clinicians with a preference. (B. Ex.-2, 15, at 56.) Paul Hatcher, M.D., considers catheters to be a commodity. (Pl. Ex.-2, 148 at 112, 136.) See also Bard Exhibit 2, 165 at 27 (noting that Memorial Hospital in Springfield, Illinois, no longer purchased from Bard; although the urologists wanted to stay with Bard, the materials manager did not). On the other hand, Daniel Humphrey, Memorial Hermann Healthcare System's chief supply chain officer, considers Foley catheters to be clinical products and purchases Bard's because the clinicians prefer them. (B. Ex.-2, 81 ¶ 13.) Similarly, Mike Brown, director of materials management at University Hospital in Augusta, Georgia, would purchase a particular catheter if the clinical committee wanted it regardless of whether the manufacturer was on Novation's contract. (B. Ex.-2, 41 at 26.) He describes commodity products as such items as shoe covers and linens. (Pl. Ex.-2, 135 at 17.) A clinical preference item involves the nursing staff. (Id.) Catheters and other urological products he considers to be clinically-driven with physician involvement with the issue of infection-control. (Id.) The clinicians at the Mayo

Foundation clinics make the buying decisions. (B. Exs.-2, 40 at 39; 144.) For instance, if a doctor or clinician wanted to order a Rochester catheter, they would, regardless of whether Rochester was on contract with their GPO, Novation. (Id. at 64, 69.) Indeed, the decision whether to use a particular catheter is clinician-physician driven. (B. Ex.-2, 198 at 21.) A University of Virginia Medical Center ("UVA") representative testified that they consider urological catheters to be clinician-preferred products. (B. Ex.-2, 34 at 18.) Gwendolyn Smith, the vice-president of the Crozer-Keystone Health System, avers that the System purchases urological products from Bard through Bard's sole source contract with Novation because the clinical staff prefers the Bard products. (B. Ex.-2, 28, ¶ 16.) Hanson testified that every urological product Bard sells is clinician preference. (B. Ex.-2, 23 at 36.)

As suggested above, hospitals tend to purchase clinician-preferred items regardless of whether the item is on a GPO contract.³³ For instance, Southeast Missouri Hospital is a member of a GPO and has a letter of commitment with Tyco for urological products. (B.

³³Testimony from various hospital representatives illustrates the reasoning behind catheters being considered a clinical-preference item. Manatee Health System switched to Bard because their nursing staff rejected the Tyco products under their GPO contract. (B. Ex.-2, 27 ¶ 8.) UVA began Bardex IC after a thirteen-month study of infection control catheters. (B. Exs.-2, 16 at 24-25; 34 at 15-16.) On the other hand, University HealthSystem Consortium stopped using Bardex IC in 2007 after there was no improvement in infection control. (Pl. Exs.-2 63, 77.) Hamot Medical Center stopped using Bardex IC because of some cuffing problems and stopped using Lubri Sil IC after experiencing an increase in catheter-associated UTIs. (Pl. Ex.-2, 73.) Henry Ford Hospital stopped using Bardex IC and changed to Tyco products after experiencing an increase in UTIs. (Pl. Ex.-2, 38.) The role that UTIs played in deciding what catheters to purchase was known by Rochester. Rochester considered its "superior antibacterial technology and . . . unique drug delivery technology" as a strength. (B. Ex.-2, 146.) The alleged superiority of its catheter over Bard's in fighting infections was an advantage it had over Bard. (B. Ex.-2, 201.) A Premier representative testified that she was concerned that Rochester's product line was "very clinical." (Pl. Ex.-2, 170 at 367.)

Ex.-2, 38 at 53, 78.) Some of their physicians prefer Bard urological catheters, so they purchase those. (Id. at 123.) John Walker, the materials management director for Indian River Medical Center, testified that Foley catheters were clinician-preference items and, although Tyco's prices were lower, the clinicians preferred Bard. (B. Ex.-2, 31 at 10.) UVA buys male external catheters off-contract from Rochester based on physician recommendations. (B. Exs.-2, 34 at 15-16; 166 at 19-20, 43-44.) The University of Utah Hospital purchases silicone catheters from Rochester although it has a GPO contract with Bard. (B. Ex.-2, 114 at 94.) Although two of the Mayo three clinics use Bardex IC, the third does not because the Foley catheter team believes that the infection rate is low enough that any incremental benefit does not offset the increase in costs. (B. Ex.-2, 198 at 19-20.) Mayo buys a significant number of silicone catheters from Tyco off-contract. (B. Ex.-2, 40 at 34, 68.) See also Bard's Exhibits-2, 106 at 18 (product review committee at WakeMed Hospitals never makes decision on what product to buy based only on whether product is on GPO contract); 58 ¶¶ 9-10 (product review team at University Hospital does not decide what product to buy based on whether manufacturer is on GPO contract); 42 at 110 (Crozer-Keystone's policy was to buy best product regardless of whether it was on GPO contract).

The significance of whether an item is a clinical-preference item is particularly evident in reference to the named plaintiff, St. Francis. The decision at St. Francis on what products to buy is made by Tegel and the clinicians. (B. Ex.-2, 33 at 14.) Tegel considers urological catheters, including Bardex IC, to be commodities. (Id. at 14-15, 64; B. Ex.-2, a42 at 112.) The majority of the catheters he purchases, however, are Bard's because the physicians prefer them although Tyco has a better price. (B. Exs.-2, 33 at 72, 106, 129; B.

Ex.-2, 142 at 112; Pl. Ex.-2, 167 at 128.) If the decision were Tegel's, he would purchase the urological catheters from Tyco. (B. Ex.-2, 33 at 115.) In Tegel's opinion, if a physician says he or she is going to use a product, then the physician will and there is not much that can be done about it. (B. Ex.-2, 185 at 30-31.) Indeed, most of the products that the physicians prefer are not on a GPO contract. It is also his opinion that no company's prices for urological catheters are fair. (B. Ex.-2, 185 at 31.) He has yet to hear why one catheter is better than another. (B. Ex.-2, 33 at 127-28.) He thinks the physicians at St. Francis prefer to use Bard catheters "on reputation alone" and disregard whether the catheters are on a GPO contract. (B. Ex.-2, 142 at 111.)

Rochester, the manufacturer consistently cited by St. Francis as proof of Bard's anti-competitive conduct, noted in its 2003 marketing plan that a strength of Bard's and Tyco's – its two primary competitors – was their extensive line of urology products and a weakness of Rochester was its limited offerings. (B. Ex.-2, 146; Pl. Ex.-2, 120 ¶¶ 2, 4.) This observation echoes one of Conway in 1999 that the lack of a full product line hindered a new company's efforts to penetrate the acute care urological product market with a new product. (B. Exs.-2, 147, 201.) A Premier representative testified that, although Rochester's infection control product was superior from an anti-microbial perspective, Rochester did not have some of the ancillary products, e.g., drainage bags, which would then have to be purchased from a different supplier. (Pl. Ex.-2, 170 at 369; Pl. Ex.-2, 171 at 134.) Part of the reason St. Francis uses Bard's urological products is that Bard was able to standardize its products. (Pl. Ex.-2, 167 at 147.) The clinical resources manager for Martin Memorial Hospital testified that the great majority of their catheters were latex and they were not interested in

a manufacturer that produced only silicone catheters. (B. Ex.-2, 158 at 18.) Moreover, they were pleased with Bard's urological catheters and had no complaints or plans to change. (Id. at 12-13.) When St. Francis started to use infection control catheters, they started to purchase all their urological products from Bard. (B. Ex.-2, 33 at 73.) It is a major undertaking to switch out a line of Foley catheters. (Pl. Ex.-2, 143 at 84.) See also Bard's Exhibit-2, 185 at 31 (It was not worth Tegel's time to switch to another company's catheters).

Bard's Form 10-K for the fiscal year ending December 31, 2007, noted that its "market position depend[ed] on its reliable product quality, dependable service and ability to develop products to meet evolving market needs." (B. Ex.-2, 1 at I-4.) In its 10-K report for the period ending September 30, 2007, Rochester recognized that other, stronger competitors had the resources to develop advanced versions of their products, possibly resulting in the obsolescence of Release NF. (B. Ex.-2, 56 at 13.) And, a key factor in the failure of another company, Baxter, to thrive in the urological catheter market, according to Benson Smith, was its failure to innovate its product line.³⁴ (B. Ex.-1, 9 at 82-83.)

Another strength recognized by Rochester as being possessed by Bard and Tyco but not, as of yet, by them is brand recognition. (B. Exs.-2, 56 at 13; 147 at 201; Pl. Ex.-2, 137 at 39-40.) The importance of brand recognition was described as a strength by Bard in its 2004 Base Urology Business Plan. (B. Ex.-2, 117 at 7.)

Discussion

³⁴Dr. Litan's reference in his report to the exit of Baxter being the "direct result" of Bard's GPO contracting practices, see Litan Report at 33, ignores this testimony and testimony that another problem with Baxter was its manufacturing location. (See B. Ex.-1, 9 at 83-84.)

Summary Judgment Standard. "Rule 56(c) [of the Federal Rules of Civil Procedure] mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." **Erenberg v. Methodist Hosp.**, 357 F.3d 787, 791 (8th Cir. 2004) (quoting **Celotex Corp. v. Catrett**, 477 U.S. 317, 322 (1986)). When ruling on a motion for summary judgment, "[t]he court must simply determine whether there exists a genuine issue for trial, i.e., whether there is sufficient evidence favoring the non-moving party for a jury to return a verdict in her favor." **Buboltz v. Residential Advantages, Inc.**, 523 F.3d 864, 870-71 (8th Cir. 2008). "The court must not weigh evidence or make credibility determinations, as those are functions for the jury." **Id.** Moreover, the facts must be viewed in the light most favorable to the nonmoving party and that party must be given the benefit of all reasonable inferences that can be drawn from the facts. **Matsushita Elec. Indus. Co. v. Zenith Radio Corp.**, 475 U.S. 574, 587 (1986); accord **Nitro Distrib., Inc. v. Alitcor, Inc.**, 565 F.3d 417, 422 (8th Cir. 2009). "'Where the record as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.'" **Id.** (quoting **Matsushita Elec. Indus.**, 475 U.S. at 587). There is no different or heightened summary judgment standard in complex antitrust cases. **Amerinet, Inc. v. Xerox Corp.**, 972 F.2d 1483, 1490 (8th Cir. 1992); accord **HDC Med., Inc. v. Minntech Corp.**, 474 F.3d 543, 546-47 (8th Cir. 2007); **Flegel v. Christian Hosp., NE-NW**, 4 F.3d 682, 685 (8th Cir. 1993).

Count I: Violation of § 1 of the Sherman Act. St. Francis alleges that Bard's agreements, whether sole source, dual source, or multi-source, with GPOs violate § 1 of the Sherman Act because they (a) require hospitals to make their urological product purchases from Bard; (b) include exclusive compliance and loyalty discounts which condition the receipt of rebates, prices, or discounts on a hospital's commitment to purchase a specified percentage of urological catheters from Bard; and (c) include penalties for purchasing other, unrelated products from other vendors. (2nd Am. Compl. ¶ 88.)

"Section 1 of the Sherman Act prohibits '[e]very contract, combination in the form of a trust or otherwise, or conspiracy, in restraint of trade or commerce.'" **Concord Boat Corp. v. Brunswick Corp.**, 207 F.3d 1039, 1058 (8th Cir. 2000) (quoting 15 U.S.C. § 1); accord Nitro Distrib., 565 F.3d at 423. "To prevail on [their] Section 1 case, [P]laintiffs must prove that: 1) there was an agreement among [Bard and GPOs] in restraint of trade; 2) [P]laintiffs were injured as *direct and proximate* result; and 3) [P]laintiffs' damages are capable of ascertainment and are not speculative." **McIntosh v. Monsanto Co.**, 462 F. Supp.2d 1025, 1029 (E.D. Mo. 2006) (emphasis added); accord Masimo Corp. v. Tyco Health Care Group, L.P., 2006 WL 1236666, *3 (C.D. Cal. 2006). "The Supreme Court has long accepted that Congress did not intend a literal interpretation of [15 U.S.C. § 1] and it has read the law as prohibiting only those practices that 'impose[] an unreasonable restraint on competition.'" **Craftsmen Limousine, Inc. v. Ford Motor Co.**, 491 F.3d 380, 386 (8th Cir.) (second alteration in original), cert. denied, 128 S.Ct. 654 (2007). Plaintiffs bear the burden of proving the unreasonableness of a restraint. **Id.**

Whether an agreement is an impermissible restraint of trade "is determined using either a per se standard or a standard that examines all of the circumstances, the so-called rule of reason." **Concord Boat**, 207 F.3d at 1058. Examples of the per se standard include price fixing, tying arrangements, and group boycotts. **Id.**; **Double D Spotting Serv., Inc. v. Supervalu, Inc.**, 136 F.3d 554, 558 (8th Cir. 1998). A sole source contract is not a group boycott. **Minnesota Ass'n of Nurse Anesthetists v. Unity Hosp.**, 208 F.3d 655, 659-60 (8th Cir. 2000). A plaintiff who has satisfied the per se standard need not prove any anticompetitive effects from the alleged restraint. **Flegel**, 4 F.3d at 685. "[C]ontracts to purchase are never *per se* violations of the antitrust laws, even in their most restrictive forms." **Advo, Inc. v. Philadelphia Newspapers, Inc.**, 51 F.3d 1191, 1204 (3rd Cir. 1995). See also **Flegel**, 4 F.3d at 686 (noting that the Eighth Circuit has not extended the per se standard to business relationships "where the economic impact of certain practices is not immediately obvious"). The GPO agreements at issue are for the purchase of urological catheters; their economic impact is not immediately, or even after study, obvious. Plaintiffs must therefore satisfy the rule of reason standard and establish anticompetitive effects from the alleged restraint. See **Minnesota Ass'n of Nurse Anesthetists**, 208 F.3d at 660 ("Exclusive dealing contracts are analyzed under the rule of reason.").

The rule of reason standard "asks whether the contract unreasonably restrains trade in a relevant product or geographic market." **Id.** at 659. The application of the rule to such a contract requires consideration of "the extent to which competition has been foreclosed in a substantial share of the relevant market, the duration of any exclusive arrangement, and the

height of entry barriers." **Concord Boat**, 207 F.3d at 1059. Also relevant is the "specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." **Craftsmen**, 491 F.3d at 387 (quoting State Oil Co. v. Khan, 522 U.S. 3, 10 (1997)). See also Flegel, 4 F.3d at 686 ("[T]he test of legality [under the rule of reason] is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.") (internal quotations omitted). "Ultimately, the goal is to determine whether restrictions in an agreement among competitors potentially harm consumers." **Virgin Atlantic Airways Ltd. v. British Airways PLC**, 69 F. Supp.2d 571, 582 (S.D. N.Y. 1999).

A rule of reason analysis begins with the properly defining the relevant market, including the product market and the geographic market. **Craftsmen**, 491 F.3d at 388. The relevant product market "includes all reasonably interchangeable products . . .," **id.** (internal quotations omitted), and "can be determined by analyzing how consumers will shift from one product to the other in response to changes in their relative costs," **HDC Med.**, 474 F.3d at 547 (internal quotations omitted). "To conduct this inquiry, the [C]ourt[] must weigh several factors including, industry or public recognition of the products as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." **Id.** (citing Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)). It is not necessary to show that every individual product had a counterpart by the competing manufacturer.

General Indus. Corp. v. Hartz Mountain Corp., 810 F.2d 795, 805-06 (8th Cir. 1987).

"[S]uch an approach to definition of the relevant product market would improperly and unrealistically fragment the market in a way not practiced even by those competing in the market." **Id.** Plaintiffs bear the burden of proving the relevant product market. **HDC Med.**, 474 F.3d at 547; accord **General Indus.**, 810 F.2d at 805.

Plaintiffs' expert, Robert E. Litan, Ph.D., defines the relevant product markets as (1) the market for the sale of Foley catheters to purchasers through GPOs and (2) the market for the sale of intermittent catheters to purchasers through GPOs. (B. Ex.-2, 121 at 4.) This definition fails for two reasons. First, it improperly manipulates the boundaries of the product market by including in the definition the tool by which Plaintiffs allege Bard is restraining trade – the GPOs.³⁵ His explanation that Foley and intermittent catheters sold through GPOs are not interchangeable with ones not sold through GPOs because of the "significant cost savings," see Litan Report at 19, includes a consideration – price – that is not relevant to the definition of a product. A GPO is not a product, or part thereof or incidental thereto. Second, Plaintiffs have not established that all Foley catheters or all intermittent catheters are reasonably interchangeable products. Rather, the evidence is that clinicians have preferences for catheters depending on whether they are latex or silicone, the reputation of the manufacturer, the presence of antimicrobial agents and the rate of infection control, whether the manufacturer has a full line of ancillary products, and whether the clinicians have experience with the catheters. See **General Indus.**, 810 F.2d at 805 ("[T]he

³⁵Dr. Litan also errs by including Integrated Delivery Networks in the relevant market. (See Litan Rep. at 16 n.17.)

reality of the marketplace must serve as the lodestar."). See also SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp., 188 F.3d 11, 23 (1st Cir. 1999) (holding that the subjective preferences of customers with specific business needs for the products of one manufacturer in a product-differentiated market "does not translate into the kind of economic power that antitrust law aims to mitigate"). Cf. Ryko Mfg. Co. v. Eden Servs., 823 F.2d 1215, 1232, n.15 (8th Cir. 1987) (finding that jury could conclude that various car-wash systems that used different equipment, i.e., rollovers, tunnel washes, and wand systems, were interchangeable after expert witness volunteered that a close geographic proximity of the three systems would harm their profitability). Indeed, the materials manager for the named Plaintiff testified that, against his instincts, he purchases Bard catheters although Tyco's are lower in price and does so because that is what the physicians want.

It is possible to find a submarket "within a more broadly defined market." H.J., Inc. v. International Tel. & Tel. Co., 867 F.2d 1531, 1540 (8th Cir. 1989).

"[T]he boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors."

Id. (quoting Brown Shoe, 370 U.S. at 325). "[T]he same proof which establishes the existence of a relevant product market also shows . . . the existence of a product submarket."

Id. Similarly, in the instant case, the same evidence that shows the lack of a relevant product market as defined by Plaintiffs also shows the lack of a submarket.

Assuming, however, that there is a relevant product market of Foley catheters and one for intermittent catheters,³⁶ Plaintiffs must still show by one of two ways that "the restraint has detrimental effects upon the competitiveness of the market."³⁷ Craftsmen, 491 F.3d at 388. The first way is to "put forth evidence of actual, sustained adverse effects on competition in the relevant market." Id. Plaintiffs have not.

The only evidence of an adverse effect of Bard's complained-of conduct relates to Foley catheters. Again, Plaintiffs use the example of Release NF to demonstrate the anti-competitiveness of this conduct. Yet, there is no evidence that any purchase of Release NF was prevented in any way by Bard's contracts with GPOs or that any hospital was required to purchase Bard's urological products. The consumers, i.e., the materials managers for various health care facilities, testified that Bard's contracts with GPOs did not prevent them from purchasing from another vendor, including Rochester. Bard's contracts with the two largest GPOs, Novation and Premier, do not preclude the GPO members from buying Rochester products. Moreover, the number of suppliers of those products increased from eight to thirteen during the class period. See Craftsmen, 491 F.3d at 390 (a decrease in the total number of competitors or reduction in overall output might reflect anticompetitive consequences). Rochester's revenue grew by 50% between 2006 and 2007; its sales force doubled in two years. Cf. General Indus., 810 F.2d at 804 (holding that jury could reasonably find that antitrust defendant used market power to prevent superior products sold

³⁶The Court notes that "[m]arket definition is not a jurisdictional prerequisite, or an issue having its own significance under the statute; it is merely an aid for determining whether power exists." General Indus., 810 F.2d at 805 (alteration in original).

³⁷It is undisputed that there are two relevant geographic markets: the United States and Missouri.

at lower prices from reaching retail shelves, thereby "preempting any opportunity for the consumer to make a real choice"; pet goods manufacturer had forced competing distributor out of business when distributor began handling, at a retailer's request, products from competing manufacturer in addition to defendant's). However, even after being granted an exemption by Novation, the percentage of its sales to Novation members did not increase. (Pl. Ex.-1, 207; B. Ex.-2 21 at 65.) On the other hand, Tyco, which was not on a Novation contract, sold Novation members 10% of their urological needs. (B. Ex.-2, 62 at 111.)

The second, more challenging way in which Plaintiffs may satisfy the "detrimental effects" element is "by making 'an inquiry into market power and market structure designed to assess the [restraint]'s actual effect.'" Craftsmen, 491 F.3d at 388 (quoting Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984)) (alteration in original). "A defendant . . . has market power if it has the ability to raise price above the competitive level without losing so many sales so rapidly that the price increase is unprofitable and must be rescinded." Id. (internal quotations omitted). The opposite has been established. Bard was awarded a sole source GPO contract with Novation in 2005 for urological products although Tyco had proposed a pricing structure that was 25% lower. (B. Ex.-2, 145.) Members of the Broadlane GPO had a price *decrease* when Bard was awarded a sole source contract after Broadlane realized that 90% of its members' purchases of urological products were from Bard and that Tyco's share of those purchases had not increased above 10% in the past nine years. (B. Ex.-2, 137.) The procurement director for another health care system negotiates lower prices with Bard than are provided on its GPO contract. (B. Ex.-2, 37 ¶ 13.) This is not the evidence of "'actual, sustained adverse effects on competition' in the general

[relevant] market," **Craftsmen**, 491 F.3d at 390 (quoting **FTC v. Independent Fed'n of Dentists**, 476 U.S. 447, 461 (1986)), that is required to establish detrimental effects.

Dr. Litan argues that Plaintiffs are not contending that GPOs are themselves anticompetitive, "[i]t is the exclusionary effects of Bard's contracts with GPOs that are anticompetitive." (B. Ex.-2, 121 at 8.) As evidence of this anticompetitive conduct, Plaintiffs point to Bard's tiered GPO contracts and rebates. As the Eighth Circuit observed in **Craftsmen**:

Any action that a profit-seeking business takes could increase its market share relative to some other segment of that market; indeed, most rational businesses actively take such steps at every available opportunity. Such steps impact competitors, but that alone does not prove an adverse impact upon the competitive process.

491 F.3d at 390-91. In **Minnesota Ass'n of Nurse Anesthetists**, the question was whether sole source agreements between hospitals and anesthesiologists constituted an injury under § 1 to nurse anesthetists whose employment with the hospitals was terminated as a result of the agreements. 208 F.3d at 657. The hospitals argued that they had entered into the agreements to eliminate billing confusion, reduce costs, and provide more efficient anesthesia services. **Id.** at 659. The Eighth Circuit noted that "[f]rom the hospitals' perspective," sole-sourcing helped achieve these goals. **Id.** at 660. The court also noted that "[e]xclusive dealing is an unreasonable restraint on trade only when a significant faction of buyers and sellers are frozen out of market by the exclusive deal." **Id.** at 661. When the sellers are numerous and the buyers large, exclusive dealing contracts may be procompetitive by "encouraging long-term, mutually advantageous business relationships." **Id.** There are multiple sellers of Foley and intermittent catheters. There is a great number of buyers of

those catheters.³⁸ Those buyers elect to use GPOs to reduce their acquisition costs and staffing needs and to simplify their billing operations. In **Concord Boat**, the Eighth Circuit found that the contracts at issue were not exclusive contracts based, in part, on the plaintiffs' expert's testimony that the plaintiff boat builders accepted the discount-program contracts of the defendant engine manufacturer "'because they individually got a deal from it. They got their discounts if they bought a lot of [defendant's] engines.'" 207 F.3d at 1058. Similarly, Dr. Litan testified that hospitals did not have to use a GPO but did "'because it is the most efficient way to get prices.'" (Pl. Ex. 198 at 137.) The court in **Concord Boat** further held that the ability of a new competitor to enter the market indicated that manufacturer's discount programs were not anticompetitive. **Id.** at 1059. Similarly, there have been five new competitors to enter the urological products market during the class period. "'Anticompetitive conduct is conduct without legitimate business purpose that makes sense only because it eliminates competition.'" **General Indus.**, 810 F.2d at 804. Bard's conduct has a legitimate business purpose.

Additionally, the "exclusive" contracts at issue are not long-term. All may be terminated on either 60 or 90 days notice. See **Concord Boat**, 207 F.3d at 1059 (rejecting § 1 claim that discount program was exclusive when program did not require purchasers to commit to manufacturer for any specified period of time). See also **Paddock Publ'ns, Inc. v. Chicago Tribune Co.**, 103 F.3d 42, 47 (7th Cir. 1996) (holding that duration of exclusive dealing contract is relevant to whether contract is illegal); **Masimo**, 2006 WL 1236666 at 5

³⁸One estimate is that there are approximately 5,000 acute care inpatient hospitals and 4500 practicing urologists. (Pl. Ex.-2, 171 at 9.)

("[E]xclusive dealing contracts [– even those requiring 100% of a customer's requirements be purchased from a single supplier –] that are terminable on short notice are not anticompetitive because foreclosure is very unlikely.").

Nor have Plaintiffs produced any evidence that Bard's use of tiered contracts and rebates is anticompetitive. In LePage's Inc. v. 3M, 324 F.3d 141 (3rd Cir. 2003), the court considered the anticompetitive effect of 3M's considerable, bundled rebates paid to customers who purchased from a set number of 3M's six product categories. Id. at 154. A customer's failure to meet the target resulted in the loss of the rebate across the line. Id. The court noted that "[t]he anticompetitive feature of package discounting is the strong incentive it gives buyers to take increasing amounts or even all of a product in order to take advantage of a discount aggregated across multiple products." Id. at 155 (quoting 2 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 794 at 83 (Supp. 2002)). Similarly, GPO members buying Bard's catheters under their contract may have an economic incentive to purchase under a tiered-commitment program and may receive rebates.³⁹ The principal anticompetitive effect of bundled rebates as offered by 3M was that "they may foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer." Id. Tyco makes a diverse group of products; Rochester does not. Rochester, however, is not the plaintiff.⁴⁰ To establish a

³⁹Those rebates may also be considerable. For instance, by buying on its Novation's contract, Memorial Hermann Healthcare System realized approximately \$6 million in rebates annually.

⁴⁰As noted above, Rochester was the plaintiff in an antitrust action against Bard, Tyco, Novation, and Premier.

antitrust violation, Plaintiffs must show that the violation caused it injury. See National Farmers' Org., Inc. v. Associated Milk Producers, Inc., 850 F.2d 1286, 1292 (8th Cir. 1988). See also In re Canadian Import Antitrust Litig., 470 F.3d 785, 791 (8th Cir. 2006) ("[A] private plaintiff must demonstrate that he has suffered an 'antitrust injury' as a result of the alleged conduct of defendant[], and that he has standing to pursue a claim under the federal antitrust laws."). Plaintiffs have not established any injury from Bard's rebates or tiered-commitment programs. Cf. LePage's, 324 F.3d at 154-57 (finding no reversible error in judgment in favor of *competing manufacturer* alleging bundled rebates of dominant manufacturer were antitrust violation); Invacare Corp. v. Respirronics, Inc., 2006 WL 3022968, *13 (N.D. Ohio 2006) (denying summary judgment in favor of defendant manufacturer on *plaintiff manufacturer's* claim that defendant had violated § 1 by entering into bundling practices that forced customers to purchase one product in order to make economically viable purchase of product that was facing competition by plaintiff). On the contrary, the court observed in LePage's, 324 F.3d at 164, that there was no testimony or evidence supporting 3M's business justification explanation in defense of its bundle rebates that customers wanted to have single invoices and shipments; Tegel supplied such evidence in the instant case. See Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 15 (1984) (holding that not every offer to sell products in a package is an antitrust violation; such conduct "can merely be an attempt to compete effectively – conduct that is entirely consistent with the Sherman Act"). There is no testimony by any hospital purchasing employee that he or she elected not to purchase a superior product in quality or price because of Bard's rebate or discount program.

It is not Rochester that is complaining of Bard's conduct; it is St. Francis in its own behalf and in behalf of other hospitals. But, St. Francis can not point to any adverse effects of Bard's conduct. Rather, St. Francis continues to buy Bard's catheters, although Tyco's are lower priced, because that is what its physicians want. Tegel negotiates agreements outside of St. Francis' two GPOs when he can obtain a better price. The alternative product Plaintiffs cite as the one that hospitals are being deprived of as a result of Bard's conduct is one that St. Francis does not want to purchase. See Flegel, 4 F.3d at 689 (rejecting § 1 claim by osteopathic urologists who were denied staff privileges at hospital and who failed to show that patients could not go to hospital that would have urologist of their choice).

Count II: Violation of § 2 of the Sherman Act. Plaintiffs next allege that Bard possesses and maintains monopoly power by engaging in the conduct complained of in Count I, in violation of § 2 of the Sherman Act.⁴¹ (2nd Am. Compl. ¶ 94.) Additionally, Bard raises barriers to entry, thereby foreclosing competition, and "artificially" fixes, raises, maintains, "and/or" stabilizes prices, thereby excluding "less expensive and/or technologically superior competitive products." (Id. ¶¶ 95, 97.)

"Section 2 of the Sherman Act prohibits 'monopoliz[ing], or attempt[ing] to monopolize . . . any part of the trade or commerce among the several States.' Concord Boat, 207 F.3d at 1060 (quoting 15 U.S.C. § 2). "To establish a Section 2 violation, [a] plaintiff[] must show that 1) the defendant possessed monopoly power in the relevant market and 2) the defendant willfully acquired or maintained this monopoly power by

⁴¹Another allegation that Bard maintained monopoly power through disparagement of competitors' products was earlier dismissed by the Court.

anticompetitive conduct as opposed to gaining that power as a result 'of a superior product, business acumen, or historical accident.'" Id. (quoting United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)). Accord Double D Spotting Serv., 136 F.3d at 560. "Monopoly power is defined as 'the power to control prices or exclude competition.'" Concord Boat, 207 F.3d at 1060 (quoting United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956)).

"Attempted monopoly claims are aimed at the employment of methods, means, and practices which would, if successful, accomplish monopolization, and which, though falling short, nevertheless approach so closely as to create a dangerous probability of it." HDC Med., 474 F.3d at 549 (quoting General Indus., 810 F.2d at 806-07). "To establish an attempted monopolization under the Sherman Act, a plaintiff must prove: '(1) a specific intent by the defendant to control prices or destroy competition; (2) predatory or anticompetitive conduct undertaken by the defendant directed to accomplishing the unlawful purpose; and (3) a dangerous probability of success.'" Id. (quoting American Tobacco Co. v. United States, 328 U.S. 781, 801 (1946)). The attempt need not "ripen into an actual monopoly" – it is the attempt which is the offense. General Indus., 810 F.2d at 807. "[A] lesser degree of market power may establish an attempted monopolization claim than that necessary to establish a completed monopolization claim." Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 100 (2nd Cir. 1998).

Moreover, "a business, especially one with a large degree of market power, may violate § 2 of the Sherman Act if it exercises its power to deal with others . . . in a manner

which is designed to unreasonably restrain trade." General Indus., 810 F.2d at 803. On the other hand, the antitrust laws do not "protect small businesses from the loss of profits due to continued competition, but only against the loss of profits from practices forbidden by the antitrust laws." Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 116 (1986).

The Court will first address whether there is a genuine issue of fact on Plaintiffs' claim of attempted monopoly, taking each of the three elements in turn.

As noted above, Plaintiffs must establish that Bard had a specific intent to destroy competition.

"The specific intent element requires proof that the defendant intended his acts to produce monopoly power" – intended to "control prices or to restrain competition unreasonably." General Indus., 810 F.2d at 801. Intent "to prevail over one's rivals" is insufficient. Id. The requisite intent may be proved by direct evidence or inferred from anticompetitive practices or other proof of unlawful conduct." Id. at 802. "An anticompetitive practice may have economic justification, but its use may be undertaken with unlawful intent and in the desire to achieve an unlawful goal." Id. (internal quotations omitted). Plaintiffs offer no probative evidence of a specific intent to destroy competition.

The only evidence of an intent by Bard to engage in anticompetitive conduct is that of Benson Smith, whose knowledge of Bard's operations predates the class period by at least five years and who now serves on the Board of a company Plaintiffs describe as Bard's competitor and former legal adversary; of an undated Bard memorandum and presentation about "fortify[ing] [Bard's] I.C. Fort" against a Tyco catheter product, see Plaintiff's Exhibits-1, 16, 56; Exhibit-2, 236; and of Bard business plan for 2005-2007 referring to

creating barriers to entry by retaining two GPO contracts through proven clinical results, economic benefits, and proprietary technology and by penetrating the market with a full line of urological products, see Plaintiff's Exhibit-1, 39. In Advo, 51 F.3d at 1199, the plaintiff presented as evidence of the defendant's specific intent the defendant's references in a business plan to an "ultimate benefit" of the complained-of conduct program being that it would be a "one-stop buy" for advertisers who would be able to consolidate their purchases of newspaper ads and circular ads and later to "upwardly adjustable" advertising rates. The court held that such corporate speech was not condemned by the antitrust statutes. Id. The plaintiff's own speech that "[w]hen [you] see the competition drowning, . . . stick a water hose down their throats" was "colorful, vigorous hyperbole," but also would not be evidence of specific intent. Id. (alterations in original). Clearly, Bard's reference in its business plan to "fortifying" its infection control catheter "fort" is not such evidence either. Plaintiffs' evidence of Bard's creation of barriers to entry is addressed below.

Specific intent may be inferred, however, from anticompetitive practices. This inquiry merges with the second element of an attempted monopoly claim – predatory or anticompetitive conduct. Insofar as Plaintiffs repeat their arguments in support of their § 1 claim as evidence of Bard's anticompetitive practices, those arguments fail for the reasons set forth above. Plaintiffs further argue that Bard's creation of barriers to entry into the urological catheter market and its pricing schemes are evidence of those practices.

Again, Plaintiffs use Rochester as the touchstone of their argument that Bard has created barriers to entry. Their choice is unavailing. Plaintiffs argue that the cost and time of obtaining FDA approval helps erect a high barrier to entry. This cost for Rochester's and

Bard's infection control catheters, see page 20, above, while not trivial is not prohibitive. Indeed, Rochester has already borne the cost and succeeded in obtaining FDA approval to market its Release NF as an infection control catheter. Tyco did not succeed, and is still able to market its Dover Silver.⁴² "A significant barrier to entry may exist when large amounts of capital would be required." **Concord Boat**, 207 F.3d at 1059. Rochester, however, has entered the infection control Foley catheter market.⁴³ It has a manufacturing location and one production line. Also, there are twelve other competitors. **Cf. United States v. Dentsply Int'l, Inc.**, 399 F.3d 181, 194 (3rd Cir. 2005) (finding competitors' "paltry penetration" of market to be indicative of high barriers to entry).

Additionally, some of the advantages Bard has that Rochester does not, e.g., a more-established reputation, a greater sales force, and greater manufacturing capabilities, are attributes that are important to GPOs when deciding contract awardees. Thus, by considering these factors when assessing contract bids, it is the GPOs that are creating the barriers to entry. **See In re Canadian Import Antitrust Litig.**, 470 F.3d at 791 (antitrust plaintiff must establish a causal connection between the alleged antitrust violation and harm to the plaintiff); **accord Concord Boat**, 207 F.3d at 1055.

⁴²The questionable significance of FDA approval is illustrated by Tyco's sales of Dover Silver. The catheter was used by one hospital and found to reduce hospital-associated urinary tract infections by 69%. (B. Ex.-2, 192 at 59.) The hospital then decided to use that catheter. (*Id.* at 59-60.) Its decision was not affected by what claims the FDA permitted Tyco to use in its advertising. (*Id.* at 61.)

⁴³Indeed, Rochester was ranked 51st in July 2007 as one of the fastest growing small public companies in the country. (B. Ex.-2, 183.)

As further proof of Bard's anticompetitive conduct, Plaintiffs cite Bard's pricing schemes.

In a predatory pricing scheme, the antitrust defendant reduces the sales price of its products to below cost with the expectation or hopes of raising those prices to a supracompetitive level after its competitor is driven out of business. Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., 549 U.S. 312, 318 (2007). In a case alleging such pricing, the plaintiff must "'demonstrate that there is a likelihood that the predatory scheme alleged would cause a rise in prices above a competitive level that would be sufficient to compensate for the amounts expended on the predation, including the time value of the money invested in it.'" Id. at 319-20 (quoting Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 225 (1993)). These schemes "'are rarely tried . . .'" Id. at 323 (quoting Brooke Group, 509 U.S. at 226). The Eighth Circuit employs two indicators when determining whether a price is predatory. Morgan v. Ponder, 892 F.2d 1355, 1360 (8th Cir. 1989). If a price is above "average total cost" – "the sum of all costs, fixed and variable, divided by total output" – it is "legal *per se*." Id. at 1360, 1360 n.11. If a price is above "average variable cost" – "the sum of all variable costs⁴⁴ . . . divided by output" – "the plaintiff must overcome a strong presumption of legality"; if a price is below average variable cost, the burden is on the defendant to show that it is not predatory pricing. Id. Additionally, "only price cutting that threatens equally or more efficient firms is condemned

⁴⁴"Variable costs" are "those costs that vary with output[.]" Morgan, 892 F.2d at 1360 n.11 (alteration added).

under Section 2." Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc., 920 F.Supp. 455, 469 (S.D. N.Y. 1996).

Plaintiffs have not shown that Bard's costs are below average variable cost. They have shown that Rochester's prices are higher and that whether Tyco or Bard has the higher price varies by situation and GPO contract. "[A]s a general rule, the exclusionary effect of prices above a relevant measure or cost either reflects the lower cost structure of the alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control." Weyerhaeuser, 549 U.S. at 319 (quoting Brooke Group, 509 U.S. at 223). There is nothing in the instant case that would preclude application of this rule.

Plaintiffs may still establish anticompetitive conduct by Bard if a buyer is forced by Bard's exploitation of control over urological catheters "into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms." Marts v. Xerox, Inc., 77 F.3d 1109, 1113 (8th Cir. 1996) (quoting Jefferson Parish Hosp. Dist No. 2 , 466 U.S. at 12). Such an arrangement might also exist if, "in addition to the other elements of a tying violation, . . . [the defendant's] pricing structure makes purchase of the tying and tied products together the only viable economic option." Ortho Diagnostic Sys., 920 F.Supp. at 471. The Third Circuit has analogized bundles rebates to tying because the foreclosure effects are similar. LePage's, 324 F.3d at 155. Thus, linking a product on which a defendant faced competition, e.g., an infection control catheter, with products on which it faced no competition could be anticompetitive behavior. Id. at 156.

This argument of Plaintiffs also is unavailing. First, a hospital could buy Bard's Foley and intermittent catheters without purchasing the other urological products. See Ortho Diagnostic Sys., 920 F.Supp. at 471 ("[I]f the tying product may be purchased without also buying the allegedly tied product, there can be no unlawful tying."). Although there is evidence that Bard included in at least some of its GPO contracts a requirement that the purchaser buy a set number of products from its various categories, there is no evidence that any consumer did so unwilling. "[T]he fact that the products are sold as part of a package at a discount price is not alone sufficient to establish the requisite tie-in." Id. (citing Jefferson Parish Hosp., 466 U.S. at 11-12). And, there is evidence that a consumer could purchase the catheters without also purchasing the other products. The named plaintiff, St. Francis, purchases from Bard because that is what their physicians want and not because, for instance, they must purchase drainage bags in order to obtain rebates on purchases of Bardex IC. The evidence also is that for ease of use and clinician preference hospitals prefer to purchase a line of catheters from one manufacturer. Second, there is no evidence that Bard's use of rebates led to higher prices. Cf. LePage's, 324 F.3d at 159 ("[E]ven the foreclosure of one significant competitor from the market may lead to higher prices and reduced output."). Third, there is no evidence that Bard's rebate program was initiated only after Rochester entered the market or that Rochester had a decrease in purchases of its Release NF after the program was initiated. Cf. Id. at 160-61 (finding it relevant that defendant introduced bundled rebate program only after plaintiff's entry into market and that demand for plaintiff's products decreased significantly following defendant's introduction of rebates). There is no evidence that a hospital did not buy from Rochester in order to obtain the rebate,

cf. id. at 160 (finding the opposite to be relevant), or that the price of catheters increased after the rebate program was initiated, cf. id. at 163 (finding the opposite to be relevant).

And, as before, there is no showing that rebate programs caused St. Francis or any other plaintiff injury.⁴⁵ "[T]he standing question under the Sherman Act requires an evaluation of the plaintiff's harm, the alleged wrongdoing by the defendant, and the relationship between them." **General Indus.**, 810 F.2d at 809. "Thus, standing to sue under the Sherman Act requires an evaluation of the plaintiff's harm, the alleged wrongdoing by the defendant, and the relationship between them." **Id.** It is "limited to a consumer or competitor that proximately suffers antitrust injury" – a "mere causal connection" is not enough. **Id.** See also Amerinet, Inc., 972 F.2d at 1490 (In order to prevail on their antitrust claim, plaintiffs must prove for each claim "an antitrust violation, the fact of damage or injury, a causal relationship between the violation and the injury, and the amount of damages") (internal quotations omitted). "Antitrust *injury, causation, and damages* all are necessary parts of the proof because 'Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation.'" **Concord Boat**, 207 F.3d at 1055 (quoting Hawaii v. Standard Oil Co., 405 U.S. 251, 262-63 n. 14 (1972)) (emphasis added). "[V]aguely defined links" in the "chain of causation" do not establish antitrust standing. **In re Canadian Import Antitrust Litig.**, 470 F.3d at 792 (quoting Associated Gen. Contractors of Calif., Inc. v. California State Council of Carpenters, 459 U.S. 519, 540 (1983)).

⁴⁵To the contrary, St. Francis participated in a Novation program because of the economic savings resulting from larger rebates. (B. Ex.-2, 33 at 47.)

Without this showing of injury, there is also no showing of damages incurred by St. Francis or any other plaintiff. St. Francis' marketing manager testified that, although Tyco has lower prices, he purchases from Bard because the hospital physicians prefer its products.⁴⁶ He also testified that he did not know if he was being denied access to any superior products because of Bard's conduct. (Pl. Ex.-2, 167 at 127; B. Ex. 2, 33 at 127.) Speculative damages are insufficient to establish a redressible antitrust injury. See Id. at 791. See also Amerinet, Inc., 972 F.2d at 1497-98 ("[W]hen a plaintiff improperly attributes all losses to a defendant's illegal acts, despite the presence of significant other factors, the evidence does not permit a jury to make a reasonable and principled estimate of the amount of damage. This is precisely the type of speculation or guesswork not permitted for antitrust jury verdicts.") (internal quotations omitted).

Count III: Violation of § 3 of the Clayton Act. "Section 3 of the Clayton Act prohibits companies from making exclusive agreements that prevent buyers from dealing in the goods⁴⁷ of a competitor where the effect of the agreements 'may be to substantially lessen competition or tend to create a monopoly.'" Masimo Corp., 2006 WL 1236666 at *3 (quoting 15 U.S.C. § 14). "Contracts imposing an obligation on a distributor to deal only in the goods of a single supplier will violate Section 3 when 'performance of the contract will foreclose competition in a substantial share of the line of commerce affected. . . . That is to

⁴⁶The importance of clinical preference in St. Francis' purchasing decisions is reflected in the decision to continue with Bardex IC and not change to Lubri Sil I.C., claimed by Bard to cut the rate of urinary tract infections by 44%. (B. Ex.-2, 60.) After conducting a trial of the Lubri Sil I.C., the clinical support team elected to stay with Bardex IC. (Id.)

⁴⁷The Clayton Act does not apply to services. See Marts, 77 F.3d at 1113 n. 7.

say, the opportunities for other traders to enter into or remain in that market must be significantly limited. . . ." Ryko Mfg. Co., 823 F.2d at 1233 (quoting Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 327-28 (1961)) (alterations in original).

In support of Count III, Plaintiffs rely on the allegations of anticompetitive conduct and of lack of business justification presented in support of the previous two counts and found to be meritless for the reasons set forth above.

Count IV: Violation of Missouri's Antitrust Law. Section 416.031.1, Mo.Rev.Stat., "provides that '[e]very contract, combination or conspiracy in restraint of trade or commerce in this state is unlawful.'" A plaintiff claiming a violation of this statute "must allege that (1) defendants contracted, conspired or combined with one another; (1) [sic] the conspiracy produced anticompetitive effects within the relevant geographic and product markets; (3) the goals of the conspiracy or combination as well as the conduct in furtherance of those goals were illegal; and (4) the plaintiff suffered injury as a result of the conspiracy." Zipper v. Health Midwest, 978 S.W.2d 398, 417 (Mo.Ct.App. 1998) (alteration in original). "Section 416.031.1 is analogous to [Section 2] of the Sherman Act. Id. at 418. "Under directive of section 416.141 . . . , federal cases interpreting Sec. 2 control interpretation of alleged violations of section 416.031.1." Id.

The Court's examination of federal cases that resulted in its conclusion that Plaintiffs' § 2 claim is without merit compels the same conclusion as to their Missouri antitrust claim.

Indirect Purchasers. Bard argues that St. Francis and other class members are indirect purchasers and therefore lack standing to sue for treble damages under § 4 of the Clayton Act, 15 U.S.C. § 15.

Section 4 provides that a person injured "by reason of anything forbidden in the antitrust laws may sue and . . . shall recover threefold the damages by him sustained." 15 U.S.C. § 15(a). Only a "direct purchaser" from a monopoly supplier can sue for treble damages under § 4.⁴⁸ **Illinois Brick Co. v. Illinois**, 431 U.S. 720, 740 (1977). "[A]n indirect purchaser [is] one who is not the immediate buyer from the alleged antitrust violator . . . or one who [does] not purchase [the monopolized product] directly from the [antitrust] defendant[.]" **Campos v. Ticketmaster Corp.**, 140 F.3d 1166, 1169 (8th Cir. 1998) (last four alterations in original). "An indirect purchaser *is* one who bears some portion of a monopoly overcharge only by virtue of an antecedent transaction between the monopolist and another, independent purchase." ***Id.*** (emphasis added). "The right to sue for damages rests with the direct purchasers, who participate in the antecedent transaction with the monopolist." ***Id.*** at 1170.

There is an exception to the direct purchaser rule that permits an indirect purchaser to recover when the direct purchaser is owned or controlled by the seller. ***Id.*** at 1171; accord **Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.**, 424 F.3d 363, 371 (3rd Cir. 2005). See also **McCarthy v. Recordex Serv. Inc.**, 80 F.3d 842, 853 (3rd 1996) (holding that in agency context question of whether direct purchaser rule applies is governed by degree of control over agent exercised by principal). This exception applies only when the relationship between the direct purchaser and seller is such that there is effectively only one sale. ***Id.***; accord **In re New Motor Vehicles Canadian Export Antitrust Litig.**, 307 F. Supp.2d 136,

⁴⁸The direct purchaser rule does not apply to requests for injunctive relief under § 16 of Clayton Act. **Campos**, 140 F.3d at 1171.

143 (D. Me. 2004). In the Eighth Circuit, however, "an antitrust plaintiff cannot avoid [the direct purchaser] rule by characterizing a direct purchaser as a party to the antitrust violation, unless the direct purchaser is joined as a defendant." Campos, 140 F.3d at 1171 n.4; accord Howard Hess, 424 F.3d at 376 (similar holding in Third Circuit).

In Delaware Valley Surgical Supply, Inc. v. Johnson & Johnson, 523 F.3d 1116 (9th Cir. 2008), the Ninth Circuit applied the direct purchaser rule to a hospital seeking treble damages under § 4 from a manufacturer of sutures, used to close wounds, and endomechanical ("endo") products, used in laparoscopic surgeries. Id. at 1118. The hospital had argued that the manufacturer was leveraging its monopoly power in sutures to create a monopoly in the endo product market. Id. The hospital was a member of Premier and purchased both products pursuant to a GPO contract. Id. As does St. Francis, the hospital ordered the manufacturer's products from a distributor. Id. at 1119. As in the instant case, the contract with the distributor provided that the hospital would pay the manufacturer the set price negotiated between the manufacturer and the GPO plus a markup percentage. Id. The hospital paid the distributor; the distributor delivered the products. Id. The court noted that it was undisputed that (a) the distributor was the immediate purchaser of the sutures and endo products; (b) the distributor paid the manufacturer for the products before selling them to the hospital; (c) the hospital paid the distributor, not the manufacturer, for the products; and (d) the distributor was an independently owned and managed company and was not an

agent or subsidiary of the hospital.⁴⁹ Id. at 1122. The court also noted the hospital's arguments:

The allegedly predatory behavior here occurred in the manufacturer's dealings with the GPOs, who were representing the hospitals' interests. Appellant[] may well be correct in positing that a hospital has a greater incentive than a distributor to bring an antitrust claim when the conduct complained of involves price negotiations with a GPO. The distributor is not a party to the initial negotiations that set the list price for its products. Such a distributor arguably has a smaller stake in contesting the price than a hospital whose representative was part of those negotiations and felt that the manufacturer was engaging in illegal behavior.

Id. at 1123. Citing the Supreme Court's holding in Kansas v. Utilicorp United, Inc., 497 U.S. 199, 218 (1990), that only the middleman could bring an antitrust suit even when that middleman passed on 100% of the overcharge to consumers, the court held that the structure of the hospital's purchases from the manufacturer did not avoid the direct purchaser rule.⁵⁰ Id. at 1123-24. See also Campos, 140 F.3d at 1171 (holding that billing practices are not determinative of indirect purchaser status – actual purchase price and cost of service fees are the single cost of attending the concert, "regardless of how that cost is divided into actual purchase price and service fees").

⁴⁹Citing the phased-out distributor agency agreements, Plaintiffs argue that the distributors are agents of Bard. This argument relies too much on form. There is no evidence of any ownership or control by Bard over the various distributors the GPO members use. There is evidence that the distributors negotiated the mark-ups with the members and that Bard has no role in such negotiations.

⁵⁰But cf. In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 19-20 (D. D.C. 2001) (finding that indirect purchase under cost-plus contract making "pass-on clearly discernable" falls within exception to direct purchaser rule), distinguished in Delaware Valley on grounds that purchasers were billed directly by defendant and paid defendant directly for product., 523 F.3d at 1125. See also McCarthy, 80 F.3d at 855 (finding viability of "cost-plus contract" exception to be doubtful in light of Utilicorp United, 497 U.S. at 216).

The Court notes that the reasoning of the Ninth Circuit is particularly persuasive in this case in which Bard has already faced antitrust claims by Rochester. The Court also notes that there is no evidence that St. Francis, the only named plaintiff, purchased its catheters directly from Bard and that a direct purchase is not a class requirement. See Howard Hess, 424 F.3d at 372-73 (plaintiffs could not avoid direct purchaser rule by alleging they were direct purchasers of drop shipments when their complaint specifically alleged that they did not directly purchase from defendant; instead rule applied because plaintiffs paid dealers, dealers took profit, and then dealers paid defendant). Therefore, the Court finds that the direct purchaser rule forecloses Plaintiffs' request for treble damages.

Conclusion

It is well established that the antitrust laws are designed to prevent harm to competition and not to competitors. See Craftsmen, 491 F.3d at 390; Flegel, 4 F.3d at 690 n.7. "[C]ompetition is the driving force behind our free enterprise system and . . . unless barriers have been erected to constrain the normal operation of the market, a court ought to exercise extreme caution because judicial intervention in a competitive situation can itself upset the balance of market forces, bringing about the very ills the antitrust laws were meant to protect." FTC v. Tenet Healthcare Corp., 186 F.3d 1045, 1055 (8th Cir. 1999).

There is no genuine issue that the antitrust violations alleged caused any proximate injury to St. Francis or other Plaintiffs. It is these Plaintiffs that are issue, not Rochester or any other urological products manufacturer. Accordingly,

IT IS HEREBY ORDERED that motion of Plaintiffs for partial summary judgment is **DENIED**. [Doc. 269]

IT IS FURTHER ORDERED that motion of C.R. Bard, Inc., for summary judgment is **GRANTED**. [Doc. 266]

IT IS FINALLY ORDERED that all other pending motions are **DENIED** as moot.

An appropriate Judgment shall accompany this Memorandum and Order.

/s/ Thomas C. Mummert, III

THOMAS C. MUMMERT, III

UNITED STATES MAGISTRATE JUDGE

Dated this 28th day of September, 2009.